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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,568	07/24/2003	Ronald C. Montclaro	I 2000.608 US C1	3285

31846 7590 10/29/2004

AKZO NOBEL PHARMA PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/627,568	MONTELARO ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

All participants (applicant, applicant's representative, PTO personnel):

(1) Bao Qun Li. (3)_____.

(2) William P. Ramey. (4)_____.

Date of Interview: 25 October 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
If Yes, brief description: _____.

Claim(s) discussed: claim 1.

Identification of prior art discussed: No.

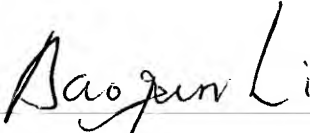
Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See attachment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Interview Summary

An interview has been conducted with Applicants' representative attorney William P. Ramey on 10/25, 2004 in view of the preliminary examination of the application. Because the specification contains several confused description, which is unable for the examiner to examine the case. He agreed to amend the application prior to further prosecution of the application by the examiner. For assisting the applicants to better describe and define what the claimed invention during the amendment, a complete explanation of the interview is summarized and mailed to applicants.

1. The specification has been carefully reviewed. The examiner notices that the following terms of "construct", "virus" "provirus" "transfection" and MOI" need to be clarified, which are confusedly used in the specification.

i). **Construct**: is **An artificial assembled DNA segment** defined by LIFE SCIENCE DICTIONARY edited by BioTech Resources and Indiana University 1995-1998. Thus, it is well accepted that the construct is used to describe a DNA molecule either in a full length or fragment thereof, including a DNA vector or a plasmid DNA. Retrovirus provirus isolated in vitro sometime can be called as proviral DNA construct because it may present as a naked DNA molecule by genetic engineered construction or reverse transcribed from a retrovirus in vitro system, which can be **transfected** into a host cell to produce a retrovirus. For the definition of provirus, please see page 499 in ILLUSTRATED DICTIONARY OF IMMUNOLOGY edited by Julius et al. 2nd edition, published by CRC Press, 2003.

ii). **Virus** is **A particle consisting of a nucleic acid (RNA or DNA) genome surrounded by a protein coat (capsid) and sometimes also a membrane**, which can replicate only after infecting a host cell. A virus particle may exist free of its host cell but it incapable of replicating on its own defined by EverythingBio.com.

iii). **Provirus**: is A DNA version of retrovirus defined by (ILLUSTRATED DICTIONARY OF IMMUNOLOGY edited by Julius et al. 2nd edition, published by CRC Press, 2003, see page 499).

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iv). **Transfection:** is an Infection of a cell with isolated viral nucleic acid followed by production of the complete virus in the cell. The definitions used in this glossary

of terminology either have been provided by the authors of the articles, or have been extracted wholly or in part, or paraphrased from the following sources: *The American Medical Association Encyclopedia of Medicine*, Charles B. Clayman, MD, Medical Editor, Random House, New York, 1989; *Dorland's Illustrated Medical Dictionary*, 28th Edition, W. B. Saunders Company, Philadelphia, 1994; *The Random House Dictionary of the English Language*, Unabridged Edition, 1966; *Webster's Ninth New Collegiate Dictionary*, 1991

v). **Infection:** Invasion and multiplication of microorganisms in body tissues.

The definitions used in this glossary of terminology either have been provided by the authors of the articles, or have been extracted wholly or in part, or paraphrased from the following sources: *The American Medical Association Encyclopedia of Medicine*, Charles B. Clayman, MD, Medical Editor, Random House, New York, 1989; *Dorland's Illustrated Medical Dictionary*, 28th Edition, W. B. Saunders Company, Philadelphia, 1994; *The Random House Dictionary of the English Language*, Unabridged Edition, 1966; *Webster's Ninth New Collegiate Dictionary*, 1991.

vi). **Multiplicity of Infection (MOI)** is an average number of phage (or virus for the eukaryotic cell) that infect a single bacterial cell in a specific experiment.

(Phage is defined as a virus that infects bacteria by EverythingBio.com).

In the instant case, specification uses the term “**construct**” in a very confusing way. First, Applicants cited the embodiment of the invention as two separate subject matters, For example, line 6 of page 2 recites: the invention pertains to an EIAV vaccine and/or construct and it further refers the vaccine as either inactivated live virus or attenuated virus, purified virus particle or whole virus particles (See lines 21-24 on page 14). Later on, the examples refers both EIAV virus and EIAV provirus DNA as a construct for “transfecting” a host cell to generate the mutated virus, which is measured sometime with DNA concentration (µg/ml) and some times measured with a virus infectious titer (MOI) (See lines 1-4 of the first paragraph of example 2 on pages 27-28, and lines 4-8 on the 2nd paragraph of page 42). The disclosure of the specification on page 42 is even more confusing in that it recites that the proviral construct by addition of 0.1% formalin prior to administer it into animals for induce an immune response.

DNA vaccine in the state of art is referred as a naked DNA construct either in a plasmid or vector DNA form that can be directly injected into a host to let the DNA molecule to express the antigenic polypeptide or peptide without any inactivation step (For definition of DNA vaccination, please see WordIQ.com). Therefore, it cannot be measured with MOI. Moreover, in general, during a DNA vaccination, the DNA construct does not need to be inactivated since it is not a live virus. A treatment of a DNA

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molecule with formalin may cause the DNA damage and unable to express the encoded polypeptide properly in a host cell as evidenced by Quach et al. (BMC Clinical Pathology 2004, Vol. 4(1) pp. 1-5).

Because the specification uses the terms motioned above sometime in a very confusing way, such that a person skill in the art is confused about which exactly material that applicants use for practicing the claimed inventions, Applicants are reminded that: 35 U.S.C. 112, first paragraph, requires the specification to be written some term in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: "mutated EIAV construct vs. proviral construct", "transfection vs. infection", and DNA concentration of " μ g" vs. virus titer of multiplicity of infection (MOI).

In particular, applicants are suggested that if the "construct" disclosed by the specification is a mutated EIAV virus, please delete the "construct" after EIAV virus, and use term of infection instead of transfection to describe the process of generating the mutated virus. If it is a virus, it can be measured with a virus titer of MOI, whereas if it is a provirus DNA construct, it can be measure with μ g/ml. However, if applicants prefer to use the term "construct" in their own way, please give a clear definition of "construct" in the specification.

For the same notion, claim 1 is also confusing for citing a construct comprising a gene mutated virus because it is improper to describe an organic naked DNA molecule comprising a microorganism.

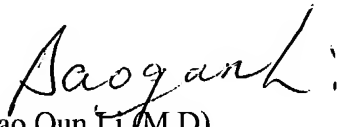
However, in view of the application, if applicants refer the claimed construct as a virus, please give a clear definition in the specification indicating what the claimed "construct" is encompassed. Because the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao Qun Li (M.D)
10/28/2004